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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,514	12/18/2001	Philip J. Barr	368292000200	6421

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EXAMINER

WALICKA, MALGORZATA A

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 07/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/025,514

Applicant(s)

BARR ET AL.

Examiner

Malgorzata A. Walicka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-10 and 12-41 is/are pending in the application.
- 4a) Of the above claim(s) 3,5-7,9,10,12-15,18-35 and 38-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2 and 4 is/are rejected.
- 7) ☒ Claim(s) 4,16,17,36 and 37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/17/02 & 4/13/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Amendment in Response to Non-final Office Action filed on April 21, 2004 is acknowledged. Claims 2, 4, 8, 16, 17, and 26 are amended. Claims 38-41 are added. Claims 2-10 and 12-41 are pending. Claims 3, 6-7, 9, 10, 12-15, 18-35 and 38-41 are withdrawn from examiner's consideration as drawn to non-elected invention. Claims 2, 4, 8, 16, 17 and 36-37 are under examination.

Detailed Office Action

1. Objections

Objection to claim 8 made in the Office Action of October 21, 2003 is withdrawn, because the claim has been amended.

2. Request for rejoinder

Applicants reiterate their request for rejoinder of method claims 26-35. As indicated in previous Office Actions, the issue will be addressed when allowable composition claims are identified.

3. Potential prior art

After reconsideration the subject matter of the article by Schasteen et al., Mol. Immunol. (1991) 28:17-26, the examiner concludes it cannot be the basis for rejection under 35 USC section 103.

4. Rejections

4.1. 35 U.S.C. 112, second paragraph

Rejection withdrawal

Rejection of claims 4, 8, 16 and 17 for lack of recitation the sequence identification number made in Office Actions of June 6, 2003 and December 3, 2002, and October 21, 2003 is withdrawn, because the claims have been amended.

The currently amended claim 2 is confusing because the claimed fusion protein has alpha 1-antitrypsin protease inhibitor activity and human secretory leukocyte protease activity. Is it Applicants' intention that the fusion protein acts exclusively against human secretory leukocyte protease? For the purpose of examination it is assumed that the inhibitory effect is against secretory leukocyte protease.

4.2. 35 U.S.C. 112, first paragraph**4.2.1. Lack of written description**

Rejection of claim 2, 4, 8 and 16-17 made in the previous Office Actions is withdrawn, because the claims have been amended and Applicants' arguments are found persuasive.

4.3. 35 U.S.C 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been

obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Australian document AU-B-13288/88 with priority date March 20, 1987 as applied to claim 2 above, and further in view of the article by Bingle L. et al., Thorax, Dec. 1996, vol. 51/12, pages 1273-1274; both documents are included in the Information Disclosure Statement.

The claims are directed to a fusion protein comprising alpha 1-antitrypsin or a functionally active portion thereof, and secretory leukocyte protease inhibitor or a functionally active portion thereof, wherein said fusion protein has alpha 1-antitrypsin activity and secretory leukocyte protease inhibitor activity.

The Australian document teaches construction of hybrid serpin that is a fusion protein comprising human secretory leukocyte protease inhibitor fused at its 3' end to exon 5 of human alpha 1-antitrypsin protease inhibitor; see Fig. 2a of the document. In addition, the document suggests, page 5, line 21: "Besides the possibility of producing hybrid serpins having altered substrate specificity or activity, the invention **provides an approach to the preparation of bifunctional proteins** ...", page 5, line 21.

Bingle et al. strongly suggest that secretory leukocyte protease inhibitor and alpha1-protease inhibitor, i.e. alpha 1-antitrypsin, are the most effective for treatment of such diseases as inflammatory lung disorders such as emphysema, bronchiectasis, pulmonary fibrosis, acute lung injury and bronchopulmonary

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displasia **when used in combination**; see page 1274, the text bridging the left and right column.

It would have been obvious to one having ordinary skill in the art at the time of invention to have a hybrid serpin as taught by the Australian document and modify it so that it contained the secretory leukocyte protease inhibitor and alpha 1-antitrypsin or their active fragments. The expectation of success was very high because the Australian document teaches the construction of fusion protein containing SLPI and part of alpha 1-antitrypsin, or any serpin, and strongly suggest construction bifunctional serpins. The motivation to combine these two serpins activities in one fusion protein was provided by Bingle et al., because they teach that combination of both activities is of high therapeutic importance. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

5. Conclusion

No claim is in conditions for allowance, however, as stated in the Office Action of June 3, 2003, the claims contain allowable subject matter. Claims 4, 16, 17, 36 and 37 are objected to as depending on rejected claim 2 but would be allowable if rewritten in an independent form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (571) 272-0944 and the right fax number is (571) 273-0944.

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The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m. EST.

If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (571) 272-0928. The fax phone number for this Group is (571) 273-0937.

Malgorzata A. Walicka, Ph.D.

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Patent Examiner



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